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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,671	12/10/2001	Otfried Kistner	V-262.00	2215
7590 04/07/2005				
Baxter healthcare Corporation				
P.O. Box 15210				
Irvine, CA 92614				
EXAMINER				
CHEN, STACY BROWN				
ART UNIT		PAPER NUMBER		
1648				

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,671

Applicant(s)

KISTNER ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-11, 14-17 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 14-17 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date _____.

- 4) ☒ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. 2/22/05 4/25/05 8/22/05
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration, filed March 3, 2004 is acknowledged. Claims 1-4, 7-11, 14-17 and 27-31 are pending and under examination. In a telephone interview on March 18, 2005, Examiner Chen and Applicant's representative, Brigitte Hajos, discussed the claims and the unexpected results of the claimed method. The discussion did not result in agreement with respect to the claims, however, the examiner indicated that the unexpected results would be considered further.

2. The interview summary of February ²⁵~~22~~, 2005 is attached to this Office Action. It appears that one page from the interview summary was not scanned into the electronic file properly. A copy of the interview summary is attached in the event that Applicant did not receive the complete interview summary of 2/²⁵~~22~~/05.

Claim Rejections - 35 USC § 103

3. Claims 1-4, 7-11, 14-17 and 27-31 remain rejected under 35 U.S.C., 103(a) as unpatentable over Dubensky Jr. *et al.* (5,789,245, herein, "Dubensky") in view of Yu *et al.* (reference AM from IDS, herein, "Yu"), both of record, and further in view of Harley *et al.*, (*Clin. Micro. Reviews*, 2001, 14(4):909-932, herein, "Harley"). The claims are drawn to a method for producing purified Ross River Virus (RRV) antigen/immunogenic compositions comprising the steps of infecting a cell culture with RRV, incubating the infected cell culture, harvesting the RRV produced, filtering through two filters and purifying the virus antigen. The specification defines "purified Ross River Virus antigen" as having greater than about 97% purity as determined by SDS-PAGE and Western blot analysis with anticellular protein specific

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antibodies and quantification of residual cellular nucleic acid. The first filter has a pore size of between about 0.3 and about 1.5 microns. The second filter has a pore size of between 0.1 and 0.5 microns.

Applicant argues that there is no motivation to look to Dubensky because Dubensky does not suggest a filter pore size of any other than 0.65 microns, while the claims are drawn to the use of a filter having a pore size of between 0.1 and 0.5 microns. Applicant points to the viral preparation of greater than about 97% purity following just two filtration steps as proof of surprising results.

In response, Applicant's arguments have been carefully considered but fail to persuade. Although the claims require that the resulting RRV composition be greater than *about* 97% pure, Applicant has not demonstrated that Dubensky's method does not result in an equally pure product. Both the Office and Applicant recognize that Dubensky does not disclose the purity of the alphavirus particles following Dubensky's two filtering steps (0.8 microns followed by filtration with a 0.65 micron filter). While Dubensky describes the product from the filtration steps as "crude", it does not follow that the product was not greater than about 97% pure. Because Dubensky's filtering steps are similar to the claimed method, and the size of the virus is known, it would have been obvious to use a filter pore size of less than 0.65 microns. Given that the diameter of an alphavirus is known, the determination of the particular filter pore size ranges employed is within the skill of the ordinary worker as a part of the process of normal optimization. One would have been motivated to use a smaller filter pore size in order to obtain a highly purified product.

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With regard to Applicant's product that is greater than about 97% pure following just two steps of filtration, the Office requests clarification. It is unclear how, after two filtration steps disclosed in the specification, the percent purity is 97%, based on the data presented in Table 1. The filtering steps certainly reduce the contaminants, however, the purity following the additional steps of benzonase and the sucrose gradient is at least 98% (page 15, paragraph [056]). Applicant is requested to explain how the purity went from 97% to just 98% after the benzonase/gradient steps when the amount of Vero cell DNA decreased from 14,000 to 1,000 pg/ml after the filtration steps during the benzonase/gradient steps.

Applicant also notes that the Office previously recognized Applicant's surprisingly pure viral preparation in the Office action of March 24, 2005, on page 5. In response, the examiner considered the results to be surprising at the time of the 3/24/05 Office Action, however, upon further consideration the results appear to be expected in view of Dubensky and the size of the virus.

Therefore, the claims remain rejected in view of the ability of one of ordinary skill in the art to optimize a known process.

Conclusion

4. No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
March 29, 2005


JAMES HOUSEL 4/4/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600